

## APPENDIX "1"

<u>Serial Number</u>	<u>What is Being Assigned</u>
1. U.S. application serial number 08/704,159	entire application and invention
2. PCT/US97/15394	entire application and invention, including any national filings

10-31-2000

U.S. Department of Commerce  
Patent and Trademark Office  
**PATENT**



101500875

**RECORDATION FORM COVER SHEET  
PATENTS ONLY**

TO: The Commissioner of Patents and Trademarks: Please record the attached original document(s) or copy(ies).

**Submission Type**

- ☒ New *9.26.00*
- ☐ Resubmission (Non-Recordation)  
Document ID#
- ☐ Correction of PTO Error  
Reel #  Frame #
- ☐ Corrective Document  
Reel #  Frame #

**Conveyance Type**

- ☒ Assignment ☐ Security Agreement
- ☐ License ☐ Change of Name
- ☐ Merger ☐ Other

**U.S. Government**  
(For Use ONLY by U.S. Government Agencies)

- ☐ Departmental File ☐ Secret File

**RECEIVED**

JAN 04 2001

**LEGAL/PATENTS**

**Conveying Party(ies)**

☐ Mark if additional names of conveying parties attached

Name (line 1)

Execution Date  
Month Day Year

Name (line 2)

**Second Party**

Name (line 1)

Execution Date  
Month Day Year

Name (line 2)

**Receiving Party**

☐ Mark if additional names of receiving parties attached

Name (line 1)

☐ If document to be recorded is an assignment and the receiving party is not domiciled in the United States, an appointment of a domestic representative is attached. (Designation must be a separate document from Assignment.)

Name (line 2)

Address (line 1)

Address (line 2)

Address (line 3)

City

State/Country

Zip Code

**Domestic Representative Name and Address**

Enter for the first Receiving Party only.

Name

Address (line 1)

Address (line 2)

Address (line 3)

Address (line 4)

**FOR OFFICE USE ONLY**

Appendix 2

NON-EXCLUSIVE PATENT LICENSE

WHEREAS Ophidian Pharmaceuticals, Inc., a Delaware corporation with a place of business at 5445 East Cheryl Parkway, Madison, Wisconsin 53711 ("OPHIDIAN"), is the owner of United States patent 5,919,665 and United States patent application serial number 08/704,159 and corresponding foreign patents and patent applications (the "'665 RELATED PATENTS")

WHEREAS the United States government has expressed a desire to acquire a license to the '665 RELATED PATENTS in order to pursue vaccine development;

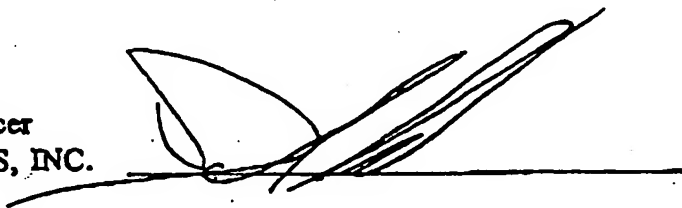
NOW, THEREFORE, in a spirit of cooperation, in view of the governments desire to pursue research towards developing a botulism vaccine, and in furtherance of its own business objectives, OPHIDIAN hereby grants to the government of the United States of America a non-exclusive, nontransferable, non-commercial, irrevocable, royalty free and paid-up license, restricted to the field of botulinum vaccine development, to make, have made, or use the inventions encompassed by the claims of the '665 RELATED PATENTS.

This Nonexclusive License has been submitted for recordation by the United States Patent and Trademark Office, is therefore effective immediately, and shall forever bind OPHIDIAN and its successors and assigns.

OPHIDIAN PHARMACEUTICALS, INC.

DATE: 24 MARCH 2000

Douglas C. Stafford, Ph.D.  
President and Chief Executive Officer  
OPHIDIAN PHARMACEUTICALS, INC.



STATE OF WISCONSIN )  
                                  ) ss.  
COUNTY OF DANE        )

On this the 24th day of March, in the year 2000, before me, the undersigned notary public, personally appeared Douglas C. Stafford, known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed above, and acknowledged that he executed the same on behalf of Ophidian Pharmaceuticals, Inc.,

-SEAL-

NOTARY PUBLIC



COMMISSION EXPIRES 9-30-2001

**CONFIDENTIAL DISCLOSURE AGREEMENT**

This Agreement is made by and between Ophidian Pharmaceuticals, Inc. (hereinafter "OPHIDIAN"), a Delaware corporation with offices at 5445 East Cheryl Parkway, Madison, WI., 53711 and Allergan, Inc., (hereinafter "Allergan") a Delaware Corporation with offices at 2525 Dupont Drive, Irvine, CA 92612. This Agreement will confirm the mutual interest of OPHIDIAN and ALLERGAN in sharing certain information and providing for protection of that information. Each party shall disclose to the other certain confidential business and technology information for the sole purpose of evaluating a business relationship.

**RECITALS.**

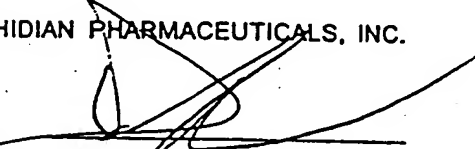
Each undersigned party, intending to be legally bound, understands that the other party (the Disclosing Party) intends to disclose information relating to the Disclosing Party's business so that the other party (the Receiving Party) may evaluate such information on the following terms and conditions:

1. Following the full execution of this Agreement, each party will disclose to the other party certain of its Confidential Information. The Confidential Information is limited to patent applications, except any portion thereof which:
  - (a.) at the time of disclosure is in the public domain;
  - (b.) after disclosure becomes part of the public domain, except by breach of this Agreement;
  - (c.) was in the possession of the recipient at the time of disclosure and was not acquired, directly or indirectly, under an obligation of confidentiality, as established by competent written evidence;
  - (d.) was received by recipient from a third party who is not, directly or indirectly, under an obligation for confidentiality to the Disclosing Party with respect to such information;
  - (e.) is required by a judicial or administrative agency of competent jurisdiction to be disclosed, after maximum practicable notice by the receiving party to the disclosing party; or,
  - (f.) was developed by or for the Recipient independent of disclosure hereunder as evidence by Recipient's written records.
2. The Receiving Party agrees not to use the Confidential Information provided by the Disclosing Party for any purpose other than the evaluation of the aforementioned business relationship.
3. The Receiving Party agrees to limit distribution of and access to Confidential Information only to employees, officers, and directors within the Receiving Party's immediate organization (and within any parent, subsidiary or affiliated entity) and outside, third party consultants bound by confidentiality requirements no less stringent than those contained within this agreement, and then only to those individuals who have a legitimate "need to know" for the above described evaluation purpose. Each party shall take all reasonable steps to ensure that such employees, whether during or after their employment with the Receiving party, shall keep the Disclosing Party's Confidential Information secret from other entities.

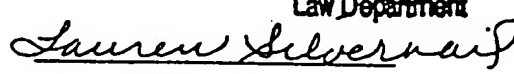
4. Receipt and evaluation of information shall be limited to a one (1) year period following the date of full execution of this Agreement, unless extended by written agreement signed by the parties. Upon thirty (30) days written notice to the other party, either party may terminate this agreement; provided, however, that all obligations of nondisclosure and non-use, as well as those provisions which by their nature should survive termination, shall so survive for a period of three (3) years from the date hereof.
5. The existence, terms, nature, or subject matter of this Agreement are confidential and shall be treated as Confidential Information pursuant to the terms of this Agreement.
6. Confidential Information received from the Disclosing Party and any developments materially derived therefrom are and shall remain the sole property of the Disclosing Party. Nothing herein shall be deemed to constitute by implication or otherwise the license or grant to the Receiving Party by the Disclosing party, except as anticipated for the purpose of this Agreement, of any intellectual property right to or interest in the Disclosing Party's information and/or any information, technology and/or products materially derived or developed therefrom, notwithstanding the exceptions set forth in Paragraph 1 herein. The Receiving Party shall not use, develop, disclose to any third party, and/or commercialize any of the foregoing without the Disclosing Party's written consent. No agency or partnership relationship is created by this Agreement; no warranties, right to use or fitness for any purpose or of any other kind are made by either Disclosing Party; and it is understood that neither party has any obligation to enter into any further agreements with the other related to any business or any other matter.
7. Nothing in this Agreement shall be deemed, by implication or otherwise to convey to the Receiving Party any rights under any patents, patents application, copyrights, trademarks, trade secrets, inventions or any other intellectual property in which the Disclosing Party has rights or interests, nor shall this Agreement be deemed a commitment of any kind by either the Receiving Party or the Disclosing Party to enter in to an future agreement with the other.
8. Each Receiving Party shall exercise due care—not less than the care accorded its own valuable Confidential Information—to prevent the unauthorized disclosure of Confidential Information received from the Disclosing Party hereunder, or its use for any purpose other than evaluation and consultation with the Disclosing party.
9. Each party represents that it has the right to make disclosures under this Agreement; that it will not disclose to the other any information confidential to any third party; and that the terms of this Agreement are not inconsistent with other contractual and/or other legal obligations it may have, or with the policies of any institution with which it is associated.
- 9.1 This Agreement shall be binding upon and inure to the benefit of the successors and assigns of the parties hereto, but neither party shall assign this Agreement without the prior written consent of the other party.

10. Upon termination of either mutual evaluations or business relations between parties, or within thirty (30) days, if otherwise requested by either party, each Receiving Party shall, upon written request, return to the Disclosing Party all written or other physical embodiments of Confidential Information (including tangible materials, unless requested by the Disclosing Party to properly destroy or dispose thereof), together with all full or partial copies thereof, as shall then be in the Receiving Party's possession, except that each party may retain one complete record copy of the other party's Confidential Information for archival purposes and to assure compliance with this Agreement.
11. This Agreement shall be governed and construed in accordance with the laws of the State of Delaware, United States of America without regard to principles of conflict of laws, and this original English language version of the Agreement shall be controlling in all respects. In the event legal action becomes necessary for the enforcement or interpretation of this Agreement such action will be brought in the US District Court for the Western District of Wisconsin, and the parties will submit to the venue and jurisdiction of said courts.
12. No course of conduct or dealing between the parties shall act as a modification or waiver of any provision of this Agreement, unless such modification or waivers are contained in writing and signed by duly authorized representative of each party

OPHIDIAN PHARMACEUTICALS, INC.

By:   
Name: Douglas C. Stafford, Ph.D.  
Title: President and CEO  
Date: 2/3/00

ALLERGAN, INC.

By:   
Name: Lauren P. Silvermail  
Title: Vice President, Business Development  
Date: 2/4/00

Approved  
Law Department

AMENDMENT TO CONFIDENTIAL DISCLOSURE AGREEMENT

THIS IS AN AMENDMENT, effective February 10, 2000, to the Confidential Disclosure Agreement which was effective February 3, 2000 between Ophidian Pharmaceuticals, Inc. ("Ophidian") and Allergan, Inc. ("Allergan") (the "Agreement")

The Agreement between the parties is hereby amended as follows:

"Confidential Information" is hereby amended to include all information in Ophidian's possession or under its control which relates in any way to any claims made by, any rights in, or any rights alleged to be owned by (a) any individual, corporation, partnership or other legal entity, or; (2) the United States or an entity, department, laboratory, or facility owned or controlled by the United States (including a U.S. Army Medical Research Institute, the U.S. Army, and/or the U.S. Department of Defense), in any of the inventions disclosed or claimed in any of (1) U.S. patent no. 5,919,665; (2) PCT application WO 96/12802; (3) U.S. patent application serial number 08/704,159, and/or; (4) PCT application WO 98/08540, including all correspondence, memoranda, internal company communications, attorney opinions or advice letters with regard to any such claims, rights or alleged rights.

All other terms and conditions of the Agreement to be unchanged.

ALLERGAN, INC.

By: Lauren P. Silvermail  
Lauren P. Silvermail  
Vice President, Business Development

Date: February 10, 2000

OPHIDIAN PHARMACEUTICALS, INC.

By: Douglas C. Stafford, PhD.

Date: February 10, 2000



520  
UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

17356-PCF

DECEMBER 23, 2000

PTAS

ALLERGAN, INC.  
STEPHEN DONOVAN  
BLDG. T2-7H  
2525 DUPONT DRIVE  
IRVINE, CA 92612



**RECEIVED**

JAN 04 2001

UNITED STATES PATENT AND TRADEMARK OFFICE  
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

**LEGAL/PATENTS**

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 09/26/2000

REEL/FRAME: 011177/0325  
NUMBER OF PAGES: 13

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

OPHIDIAN PHARMACEUTICALS, INC.

DOC DATE: 03/31/2000

ASSIGNEE:

ALLERGAN, INC.  
2525 DUPONT DRIVE  
IRVINE, CALIFORNIA 92612

SERIAL NUMBER: 08405496  
PATENT NUMBER: 5919665

FILING DATE: 03/16/1995  
ISSUE DATE: 07/06/1999

SERIAL NUMBER:  
PATENT NUMBER:  
PCT NUMBER: US9513737

FILING DATE:  
ISSUE DATE:



011177/0325 PAGE 2

TARA WASHINGTON, EXAMINER  
ASSIGNMENT DIVISION  
OFFICE OF PUBLIC RECORDS

the scope of articles 1 or 2 above. Thus, the right of first negotiation set forth in this article 3 with regard to a license does not come into effect until March 21, 2005. The right of first negotiation set forth in this article 3 with regard to an assignment comes into effect as of March 21, 2000.

4. In consideration of the foregoing, within ten (10) days of the effective date of this Agreement, ALLERGAN agrees to deliver to OPHIDIAN

5. ALLERGAN acknowledges that the assignment of the PATENT ESTATE is subject to a license granted by OPHIDIAN to the United States of America, a copy of which license is attached hereto as Appendix 2 (the LICENSE"). ALLERGAN understands and acknowledges that, as the assignee of the PATENT ESTATE, it is bound by the terms of the LICENSE.

6. Within seven (7) days of the effective date of this Agreement, OPHIDIAN shall submit the LICENSE to the U.S. Patent and Trademark Office for recordation, and shall also simultaneously furnish a copy of the LICENSE to appropriate United States government officials as notice to the licensee of the granting of the LICENSE.

7. OPHIDIAN agrees to cooperate fully, at ALLERGAN's expense, to assist ALLERGAN in executing and filing such documents as may be necessary or prudent to vest ownership of the PATENT ESTATE in ALLERGAN. OPHIDIAN also agrees to cooperate fully, at ALLERGAN's expense, to assist ALLERGAN in prosecuting, enforcing or defending any of the PATENT ESTATE, and OPHIDIAN further covenants and agrees that it will communicate to ALLERGAN or to its successors, legal representatives and assigns, any facts known to it regarding the PATENT ESTATE, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuation-in-part, continuing and reissue applications, make all rightful oaths and generally do everything possible to aid ALLERGAN or its successors, legal representatives and assigns, to obtain and enforce proper patent protection for the PATENT ESTATE in all countries.

8. OPHIDIAN and its employees and officers agree to sign and promptly return to ALLERGAN all required documents such as declarations of inventorship, assignment documents and patent prosecution related documents and declarations so that ALLERGAN can file and expeditiously prosecute one or more patent applications, as it may decide in relation to the PATENT ESTATE.

9. OPHIDIAN represents and warrants that it owns the entire right, title and interest in the PATENT ESTATE and that it has full power and authority to enter into this Agreement.

10. OPHIDIAN hereby represents and warrants that it has no knowledge, except as otherwise disclosed to ALLERGAN prior to the signing of this Agreement,

that the exercise of the PATENT ESTATE would or might infringe the rights, including patent rights, of any third party, and that it has no knowledge of and that no claims have been made from which it can be inferred that any claim of any patent or application encompassed by the PATENT ESTATE is or may be invalid.

11. The parties hereto shall consult with each other before issuing any public announcement or press release, or otherwise making any public statement with respect to this Agreement, or the subject matter hereof and neither of them shall issue or make any public statement prior to obtaining the other party's approval, which approval shall not be unreasonably withheld or delayed. No such approval shall be necessary to the extent disclosure may be required by applicable law or the rules or regulation of any stock exchange. However the party preparing to make any such disclosure shall provide the other party reasonable prior notice of the timing and content of any such disclosure. The parties will use reasonable efforts to coordinate an initial public statement, if any, relating to this Agreement so that any such public statement by each party can be made contemporaneously.

12. OPHIDIAN agrees that it will not challenge the validity, scope or enforceability of any of the PATENT ESTATE.

13. The parties' confidential disclosure agreement executed on 3 February 2000 and modified 10 February 2000 is attached hereto and incorporated herein by reference.

14. This Agreement may be amended or modified only by written instrument executed by all the parties hereto.

15. Notices shall be in writing and may be delivered by certified mail addressed to the parties at the addresses listed at the beginning of this agreement or such other address as either party may direct by written notice. Notices shall be deemed to have been given upon actual receipt or within three (3) days of mailing by first class mail in the United States of America.

16. The relationship of the parties under this Agreement is one of independent contractors only. In no event shall either party, or any of its employees, agents, servants or contractors be deemed agents or employees of the other party. Neither party has any authority to bind or obligate or incur any liability on behalf of the other, and no such authority shall be implied.

17. Any controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be settled by binding arbitration by an entity, such as JAMS or ENDISPUTE which uses retired judicial officers as arbitrators, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The parties shall bear their own costs of arbitration, and shall bear an equal share of the arbitrator's fees and expenses unless the arbitrator finds that the party seeking arbitration is acting in bad faith, or frivolously, or in a manner

calculated to harass the defending party, in which case the arbitrator may assess all or a greater portion of the costs of arbitration, including actual attorneys fees, against the party who originally sought the arbitration. If arbitration is requested by ALLERGAN, any arbitration proceeding will take place in Wisconsin applying Wisconsin law. If arbitration is requested by OPHIDIAN, any arbitration proceeding will take place in California applying California law.

18. This Agreement shall be binding upon and enure to the benefit of the parties hereto and to their successors and assigns.

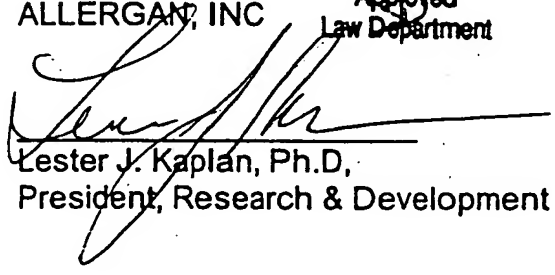
19. This agreement constitutes the entire understanding between the parties with respect to the subject matter hereof and may be amended or modified only by written instrument executed by all the parties hereto. This agreement supercedes all previous communications, representations, understandings and agreements, either oral or written, between the parties or any official or representative thereof with respect to the subject of this Agreement. No representations or warranties are given by either party except for those set forth herein.

IN WITNESS WHEREOF, the parties hereto have affixed their signatures as of the date shown given.

OPHIDIAN PHARMACEUTICALS, INC

  
Douglas C. Stafford, Ph.D.  
President and Chief Executive Officer

ALLERGAN, INC

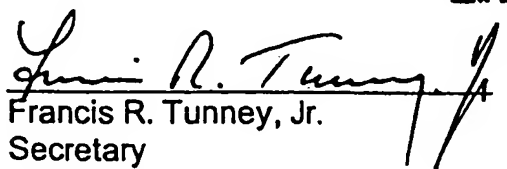
  
Lester J. Kaplan, Ph.D.,  
President, Research & Development

Approved  
Law Department

Date: March 29, 2000

Date: March 31, 2000

ALLERGAN BOTOX LIMITED

  
Francis R. Tunney, Jr.  
Secretary

Approved  
Law Department

Date: March 31, 2000



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17350  
UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

DECEMBER 23, 2000

PTAS



\*101500875A\*

ALLERGAN, INC.  
STEPHEN DONOVAN  
BLDG. T2-7H  
2525 DUPONT DRIVE  
IRVINE, CA 92612

**RECEIVED**

UNITED STATES PATENT AND TRADEMARK OFFICE  
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

JAN 04 2001

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**LEGAL PATENTS**

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RECORDATION DATE: 09/26/2000

REEL/FRAME: 011183/0764  
NUMBER OF PAGES: 12

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

OPHIDIAN PHARMACEUTICALS, INC.

DOC DATE: 03/31/2000

ASSIGNEE:

ALLERGAN, INC.  
ALLERGAN BOTOX LIMITED  
2525 DUPONT DRIVE  
IRVINE, CALIFORNIA 92612

SERIAL NUMBER: 08704159  
PATENT NUMBER:

FILING DATE: 08/28/1996  
ISSUE DATE:

TONYA LEE, EXAMINER  
ASSIGNMENT DIVISION  
OFFICE OF PUBLIC RECORDS

**Correspondent Name and Address**

Area Code and Telephone Number **714 246 4026**

Name **Stephen Donovan**

Address (line 1) **Allergan, Inc.**

Address (line 2) **Bldg. T2-7H**

Address (line 3) **2525 Dupont Drive**

Address (line 4) **Irvine, CA 92612**

**Pages**

Enter the total number of pages of the attached conveyance document including any attachments. # **1**

**Application Number(s) or Patent Number(s)**

☐ Mark if additional numbers attached

Enter either the Patent Application Number or the Patent Number (DO NOT ENTER BOTH numbers for the same property).

Patent Application Number(s)

Patent Number(s)

**US08/704,159**

If this document is being filed together with a new Patent Application, enter the date the patent application was signed by the first named executing inventor.

Month Day Year  
**01 08 85**

**Patent Cooperation Treaty (PCT)**

Enter PCT application number  
only if a U.S. Application Number  
has not been assigned.

PCT **US97/15394**

PCT

PCT

PCT

PCT

PCT

**Number of Properties**

Enter the total number of properties involved. # **2**

**Fee Amount**

Fee Amount for Properties Listed (37 CFR 3.41): \$ **80.00**

Method of Payment:  
Deposit Account

Enclosed ☐

Deposit Account ☒

(Enter for payment by deposit account or if additional fees can be charged to the account.)

Deposit Account Number:

# **01-0885**

Authorization to charge additional fees:

Yes ☒

No ☐

**Statement and Signature**

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document. Charges to deposit account are authorized, as indicated herein.

**Stephen Donovan**

Name of Person Signing

Registration No. 33,433

Signature

Date

**9/26/00**

## AGREEMENT

THIS AGREEMENT has an effective date of March 21, 2000 and is between Ophidian Pharmaceuticals, Inc., a Delaware Corporation having a place of business at 5445 East Cheryl Parkway, Madison, Wisconsin 53711 ("OPHIDIAN") and Allergan, Inc., a Delaware Corporation, having a place of business at 2525 Dupont Drive, Irvine, California 92612, and its affiliate Allergan Botox Limited, an Irish corporation (collectively "ALLERGAN").

WHEREAS OPHIDIAN is the owner of certain patents and patent applications relating to recombinant botulinum toxins;

WHEREAS, ALLERGAN wishes to acquire the entire right, title and interest in and to the recombinant botulinum toxins patents and applications owned by OPHIDIAN;

NOW, THEREFORE, THE PARTIES AGREE AS FOLLOWS:

"PATENT ESTATE" means the patents and patent applications set forth on the attached Appendix 1.

1. Upon the receipt of payment as set forth in paragraph 4, OPHIDIAN hereby sells, assigns, transfers and sets over to ALLERGAN, all right, title and interest, throughout the world, possessed by OPHIDIAN in and to the PATENT ESTATE.
2. Upon the receipt of payment as set forth in paragraph 4, OPHIDIAN hereby grants ALLERGAN a royalty free, fully paid up, and irrevocable license in and to any claims in any United States patents and patent applications (and resulting patent or patents), and to any foreign patents and patent applications (and resulting patent or patents), owned by OPHIDIAN or in which OPHIDIAN acquires rights in or to within a five-year period subsequent to the date of this Agreement, which claims cover any non-type A recombinant botulinum toxin or a derivative or fragment thereof, or a process for making or using any non-type A recombinant botulinum toxin or derivative or fragment thereof, and which is not set forth on the attached Appendix A ("ADDITIONAL PATENT ESTATE"). This license will expire when there is no longer at least one patent within the ADDITIONAL PATENT ESTATE which has at least one unexpired claim.
3. Upon the receipt of payment as set forth in paragraph 4, OPHIDIAN hereby grants ALLERGAN a right of first negotiation regarding any assignment of or license to any claims of any United States patent or patent application, and to any foreign patent or patent application, owned by OPHIDIAN or in which OPHIDIAN acquires rights in or to, which claims cover any non-type A recombinant botulinum toxin or a derivative or fragment thereof, or a process for making or using any non-type A recombinant botulinum toxin or derivative or fragment, and which is not within

10-31-2000



101500876

U.S. Department of Commerce  
Patent and Trademark Office  
**PATENT****RECORDATION FORM COVER SHEET  
PATENTS ONLY**

TO: The Commissioner of Patents and Trademarks: Please record the attached original document(s) or copy(ies).

**Submission Type**☒ New  
☐ Resubmission (Non-Recordation)  
Document ID# ☐ Correction of PTO ErrorReel # Frame # ☐ Corrective DocumentReel # Frame # **Conveyance Type**☒ Assignment☐ Security Agreement☐ License☐ Change of Name☐ Merger☐ OtherU.S. Government  
(For Use ONLY by U.S. Government Agencies)☐ Departmental File☐ Secret File**RECEIVED**

JAN 04 2001

**LEGAL/PATENTS****Conveying Party(ies)**☐ Mark if additional names of conveying parties attached

Name (line 1)

Ophidian Pharmaceuticals, Inc.

Execution Date  
Month Day Year

03/31/2000

Name (line 2)

**Second Party**

Name (line 1)

Execution Date  
Month Day Year

Name (line 2)

**Receiving Party**☐ Mark if additional names of receiving parties attached

Name (line 1)

Allergan, Inc.

Name (line 2)

Allergan Botox Limited

Address (line 1)

2525 Dupont Drive

Address (line 2)

Address (line 3)

Irvine

California

92612

City

State/Country

Zip Code

☐ If document to be recorded is an assignment and the receiving party is not domiciled in the United States, an appointment of a domestic representative is attached. (Designation must be a separate document from Assignment.)**Domestic Representative Name and Address**

Enter for the first Receiving Party only.

Name

Address (line 1)

Address (line 2)

Address (line 3)

Address (line 4)

**FOR OFFICE USE ONLY**

Public burden reporting for this collection of information is estimated to average approximately 30 minutes per Cover Sheet to be recorded, including time for reviewing the document and gathering the data needed to complete the Cover Sheet. Send comments regarding this burden estimate to the U.S. Patent and Trademark Office, Chief Information Officer, Washington, D.C. 20231 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Paperwork Reduction Project (0651-0027), Washington, D.C. 20503. See OMB Information Collection Budget Package 0651-0027, Patent and Trademark Assignment Practices. DO NOT SEND REQUESTS TO RECORD ASSIGNMENT DOCUMENTS TO THIS ADDRESS.

Mail documents to be recorded with required cover sheet(s) information to:  
Commissioner of Patents and Trademarks, Box Assignments, Washington, D.C. 20231



**Correspondent Name and Address**

Area Cod and Telephone Number **714 246 4026**

Name **Stephen Donovan**

Address (line 1) **Allergan, Inc.**

Address (line 2) **Bldg. T2-7H**

Address (line 3) **2525 Dupont Drive**

Address (line 4) **Irvine, CA 92612**

**Pages**

Enter the total number of pages of the attached conveyance document including any attachments. # **3**

**Application Number(s) or Patent Number(s)**

☐ Mark if additional numbers attached

Enter either the Patent Application Number or the Patent Number (DO NOT ENTER BOTH numbers for the same property).

Patent Application Number(s)

Patent Number(s)


**US 5919,665**  
**South Africa**  
**95/8990**


If this document is being filed together with a new Patent Application, enter the date the patent application was signed by the first named executing inventor.

Month Day Year  
**9 26 99**

**Patent Cooperation Treaty (PCT)**

Enter PCT application number  
only if a U.S. Application Number  
has not been assigned.

PCT **US95/13737**

PCT

PCT

PCT

PCT

PCT

**Number of Properties**

Enter the total number of properties involved. # **3**

**Fee Amount**

Fee Amount for Properties Listed (37 CFR 3.41): \$ **120.00**

Method of Payment:  
Deposit Account

Enclosed ☐

Deposit Account ☒

(Enter for payment by deposit account or if additional fees can be charged to the account.)

Deposit Account Number:

# **01-0885**

Authorization to charge additional fees:

Yes

☒

No

☐

**Statement and Signature**

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document. Charges to deposit account are authorized, as indicated herein.

**Stephen Donovan**

Name of Person Signing

Registration No. 33,433



Signature

**9/26/99**

Date

## AGREEMENT

THIS AGREEMENT has an effective date of March 21, 2000 and is between Ophidian Pharmaceuticals, Inc., a Delaware Corporation having a place of business at 5445 East Cheryl Parkway, Madison, Wisconsin 53711 ("OPHIDIAN") and Allergan, Inc., a Delaware Corporation, having a place of business at 2525 Dupont Drive, Irvine, California 92612, and its affiliate Allergan Botox Limited, an Irish corporation (collectively "ALLERGAN").

WHEREAS OPHIDIAN is the owner of certain patents and patent applications relating to recombinant botulinum toxins;

WHEREAS, ALLERGAN wishes to acquire the entire right, title and interest in and to the recombinant botulinum toxins patents and applications owned by OPHIDIAN;

NOW, THEREFORE, THE PARTIES AGREE AS FOLLOWS:

"PATENT PROPERTIES" means the patents and patent applications set forth on the attached Appendix A.

1. Upon receipt of payment as set forth in paragraph 4, OPHIDIAN hereby sells, assigns, transfers and sets over to ALLERGAN, all right, title and interest, throughout the world, possessed by OPHIDIAN in and to the PATENT PROPERTIES.
2. Upon receipt of payment as set forth in paragraph 4, OPHIDIAN hereby grants ALLERGAN a royalty free, fully paid up, and irrevocable license in and to any claims in any United States patents and patent applications (and resulting patent or patents), and to any foreign patents and patent applications (and resulting patent or patents), currently owned by OPHIDIAN or in which OPHIDIAN acquires rights in or to within a five year period subsequent to the effective date of this Agreement, which claims cover any type A recombinant botulinum toxin or a derivative or fragment thereof, or a process for making or using any type A recombinant botulinum toxin or derivative or fragment thereof, and which is not set forth on the attached Appendix A ("ADDITIONAL PATENT PROPERTIES"). This license will expire when there is no longer at least one patent within the ADDITIONAL PATENT PROPERTIES which has at least one unexpired claim.
3. Upon receipt of payment as set forth in paragraph 4, OPHIDIAN hereby grants ALLERGAN a right of first negotiation regarding any assignment of or license to any claim in any United States patent or patent application, and to any foreign patent or patent application, owned by OPHIDIAN or in which OPHIDIAN acquires rights in or to, which claims cover any type A recombinant botulinum toxin or a derivative or fragment thereof, or a process for making or using any type A recombinant botulinum toxin or derivative or fragment, and which is not within the

scope of articles 1 or 2 above. Thus, the right of first negotiation set forth in this article 3 with regard to a license does not come into effect until March 21, 2005. The right of first negotiation set forth in this article 3 with regard to an assignment comes into effect as of March 21, 2000.

4. In consideration of the foregoing, within ten (10) days of the effective date of this Agreement, ALLERGAN agrees to deliver to OPHIDIAN

5. ALLERGAN acknowledges that the assignment of the PATENT PROPERTIES is subject to a license granted by OPHIDIAN to the United States of America, a copy of which license is attached hereto as Appendix "B" (the LICENSE). ALLERGAN understands and acknowledges that, as the assignee of the PATENT PROPERTIES, it is bound by the terms of the LICENSE. ALLERGAN grants an exclusive license back to OPHIDIAN as to the claims of the South African Patent 95/8990 directed to C. difficile (see LICENSE B attached as Appendix C).

6. Within seven (7) days of the effective date of this Agreement, OPHIDIAN shall submit the executed LICENSE to the U.S. Patent and Trademark Office for recordation, and shall also furnish a copy of the LICENSE to appropriate United States government officials as notice to the licensee of the granting of the LICENSE.

7. OPHIDIAN agrees to cooperate fully, at ALLERGAN's expense, to assist ALLERGAN in executing and filing such documents as may be necessary or prudent to vest ownership of the PATENT PROPERTIES in ALLERGAN. OPHIDIAN also agrees to cooperate fully, at ALLERGAN's expense, to assist ALLERGAN in prosecuting, enforcing or defending any of the PATENT PROPERTIES, and OPHIDIAN further covenants and agrees that it will communicate to ALLERGAN or to its successors, legal representatives and assigns, any facts known to it regarding the PATENT PROPERTIES, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuation-in-part, continuing and reissue applications, make all rightful oaths and generally do everything possible to aid ALLERGAN or its successors, legal representatives and assigns, to obtain and enforce proper patent protection for the PATENT PROPERTIES in all countries.

8. OPHIDIAN and its employees and officers agree to sign and promptly return to ALLERGAN all required documents such as declarations of inventorship, assignment documents and patent prosecution related documents and declarations so that ALLERGAN can file and expeditiously prosecute one or more patent applications, as it may decide in relation to the PATENT PROPERTIES.

9. OPHIDIAN represents and warrants that it owns the entire right, title and interest in the PATENT PROPERTIES and that it has full power and authority to enter into this Agreement.

10. OPHIDIAN hereby represents and warrants that it has no knowledge, except as otherwise disclosed to ALLERGAN prior to the signing of this Agreement, that the exercise of the PATENT PROPERTIES would or might infringe the rights, including patent rights, of any third party, and that it has no knowledge of and that no claims have been made from which it can be inferred that any claim of any patent or application encompassed by the PATENT PROPERTIES is or may be invalid.

11. The parties hereto shall consult with each other before issuing any public announcement or press release, or otherwise making any public statement with respect to this Agreement, or the subject matter hereof and neither of them shall issue or make any public statement prior to obtaining the other party's approval, which approval shall not be unreasonably withheld or delayed. No such approval shall be necessary to the extent disclosure may be required by applicable law or the rules or regulation of any stock exchange. However the party preparing to make any such disclosure shall provide the other party reasonable prior notice of the timing and content of any such disclosure. The parties will use reasonable efforts to coordinate an initial public statement, if any, relating to this Agreement so that any such public statement by each party can be made contemporaneously.

12. OPHIDIAN agrees that it will not challenge the validity, scope or enforceability of any of the PATENT PROPERTIES.

13. The parties' confidential disclosure agreement executed on 3 February 2000 and modified 10 February 2000 is attached hereto and incorporated herein by reference.

14. This Agreement may be amended or modified only by written instrument executed by all the parties hereto.

15. Notices shall be in writing and may be delivered by certified mail addressed to the parties at the addresses listed at the beginning of this agreement or such other address as either party may direct by written notice. Notices shall be deemed to have been given upon actual receipt or within three (3) days of mailing by first class mail in the United States of America.

16. The relationship of the parties under this Agreement is one of independent contractors only. In no event shall either party, or any of its employees, agents, servants or contractors be deemed agents or employees of the other party. Neither party has any authority to bind or obligate or incur any liability on behalf of the other, and no such authority shall be implied.

17. Any controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be settled by binding arbitration by an entity, such as JAMS or ENDISPUTE which uses retired judicial officers as arbitrators, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The parties shall bear their own costs of arbitration, and shall

bear an equal share of the arbitrator's fees and expenses unless the arbitrator finds that the party seeking arbitration is acting in bad faith, or frivolously, or in a manner calculated to harass the defending party, in which case the arbitrator may assess all or a greater portion of the costs of arbitration, including actual attorneys fees, against the party who originally sought the arbitration. If arbitration is requested by ALLERGAN, any arbitration proceeding will take place in Wisconsin applying Wisconsin law. If arbitration is requested by OPHIDIAN, any arbitration proceeding will take place in California applying California law.

18. This Agreement shall be binding upon and enure to the benefit of the parties hereto and to their successors and assigns.

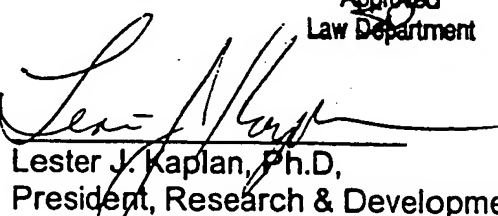
19. This agreement constitutes the entire understanding between the parties with respect to the subject matter hereof and may be amended or modified only by written instrument executed by all the parties hereto. This agreement supercedes all previous communications, representations, understandings and agreements, either oral or written, between the parties or any official or representative thereof with respect to the subject of this Agreement. No representations or warranties are given by either party except for those set forth herein.

IN WITNESS WHEREOF, the parties hereto have affixed their signatures as of the date shown given.

OPHIDIAN PHARMACEUTICALS, INC.

  
Douglas C. Stafford, Ph.D.  
President and Chief Executive Officer

ALLERGAN, INC

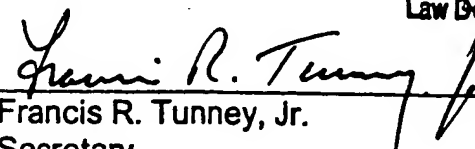
  
Lester J. Kaplan, Ph.D.,  
President, Research & Development

Approved  
Law Department

Date: March 29, 2000

Date: March 31, 2000

ALLERGAN BOTOX LIMITED

  
Francis R. Tunney, Jr.  
Secretary

Approved  
Law Department

Date: March 31, 2000

## APPENDIX "A"

<u>Serial Number</u>	<u>What is Assigned By This Agreement</u>
1. U.S. Patent 5,919,665	The entire patent
2. PCT/US95/13737 (WO 96/12802)	<p>The invention, application and subject matter of claims 1-35 , including any divisional application relating to claims 1-35, and any national filings relating to any of the subject matter of claims 1-35 .</p> <p>The subject matter of claims 36-129 which relates to non-botulinum subject matter, is retained by OPHIDIAN.</p>
3. South African Patent 95/8990	The entire patent (with a license back to Ophidian as set forth in the Agreement)

Appendix B

NON-EXCLUSIVE PATENT LICENSE

WHEREAS Ophidian Pharmaceuticals, Inc., a Delaware corporation with a place of business at 5445 East Cheryl Parkway, Madison, Wisconsin 53711 ("OPHIDIAN"), is the owner of United States patent 5,919,665 and United States patent application serial number 08/704,159 and corresponding foreign patents and patent applications ( the "'665 RELATED PATENTS")

WHEREAS the United States government has expressed a desire to acquire a license to the '665 RELATED PATENTS in order to pursue vaccine development;

NOW, THEREFORE, in a spirit of cooperation, in view of the governments desire to pursue research towards developing a botulism vaccine, and in furtherance of its own business objectives, OPHIDIAN hereby grants to the government of the United States of America a non-exclusive, nontransferable, non-commercial, irrevocable, royalty free and paid-up license, restricted to the field of botulinum vaccine development, to make, have made, or use the inventions encompassed by the claims of the '665 RELATED PATENTS.

This Nonexclusive License has been submitted for recordation by the United States Patent and Trademark Office, is therefore effective immediately, and shall forever bind OPHIDIAN and its successors and assigns.

OPHIDIAN PHARMACEUTICALS, INC.

DATE: 27 MARCH 2000

Douglas C. Stafford, Ph.D.  
President and Chief Executive Officer  
OPHIDIAN PHARMACEUTICALS, INC.



STATE OF WISCONSIN )  
                                  ) ss.  
COUNTY OF DANE        )

On this the 27th day of March, in the year 2000, before me, the undersigned notary public, personally appeared Douglas C. Stafford, known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed above, and acknowledged that he executed the same on behalf of Ophidian Pharmaceuticals, Inc.,

-SEAL-

NOTARY PUBLIC



COMMISSION EXPIRES 9-30-2001

## APPENDIX C

### EXCLUSIVE PATENT LICENSE (LICENSE B)

WHEREAS, Allergan, Inc., a Delaware Corporation, having a place of business at 2525 Dupont Drive, Irvine, California 92612, and its affiliate Allergan Botox Limited, an Irish corporation (collectively "ALLERGAN"), has acquired ownership of South African Patent 95/8990 pursuant to the AGREEMENT attached hereto.

WHEREAS, Ophidian Pharmaceuticals, Inc. a Delaware corporation with a place of business at 5445 East Cheryl Parkway, Madison Wisconsin 53711 ("OPHIDIAN"), has expressed a desire to acquire an exclusive license to the C. difficile claims of the South African Patent 95/8990.

NOW, THEREFORE, in a spirit of cooperation, in view of OPHIDIAN's desire to pursue its own business objectives, ALLERGAN hereby grants to OPHIDIAN an exclusive, royalty free and fully paid-up license, restricted to claims 35-101 (the C. difficile claims) in South African Patent 95/8990, to make, have made, or use the inventions encompassed by these claims.

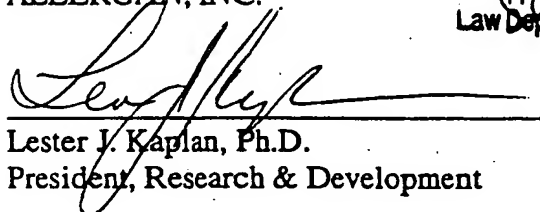
This exclusive License has been submitted for recordation by the United States Patent and Trademark Office, is therefore effective immediately, and shall forever bind ALLERGAN and its successors and assigns.

OPHIDIAN PHARMACEUTICALS, INC.

  
Douglas C. Stafford, Ph.D.  
President and Chief Executive Officer

Date: March 29, 2000

ALLERGAN, INC.

  
Lester J. Kaplan, Ph.D.  
President, Research & Development

Date: March 31, 2000

Approved  
Law Department



**CONFIDENTIAL DISCLOSURE AGREEMENT**

This Agreement is made by and between Ophidian Pharmaceuticals, Inc. (hereinafter "OPHIDIAN"), a Delaware corporation with offices at 5445 East Cheryl Parkway, Madison, WI., 53711 and Allergan, Inc., (hereinafter "Allergan") a Delaware Corporation with offices at 2525 Dupont Drive, Irvine, CA 92612. This Agreement will confirm the mutual interest of OPHIDIAN and ALLERGAN in sharing certain information and providing for protection of that information. Each party shall disclose to the other certain confidential business and technology information for the sole purpose of evaluating a business relationship.

**RECITALS**

Each undersigned party, intending to be legally bound, understands that the other party (the Disclosing Party) intends to disclose information relating to the Disclosing Party's business so that the other party (the Receiving Party) may evaluate such information on the following terms and conditions:

1. Following the full execution of this Agreement, each party will disclose to the other party certain of its Confidential Information. The Confidential Information is limited to patent applications, except any portion thereof which:
  - (a.) at the time of disclosure is in the public domain;
  - (b.) after disclosure becomes part of the public domain, except by breach of this Agreement;
  - (c.) was in the possession of the recipient at the time of disclosure and was not acquired, directly or indirectly, under an obligation of confidentiality, as established by competent written evidence;
  - (d.) was received by recipient from a third party who is not, directly or indirectly, under an obligation for confidentiality to the Disclosing Party with respect to such information;
  - (e.) is required by a judicial or administrative agency of competent jurisdiction to be disclosed, after maximum practicable notice by the receiving party to the disclosing party; or,
  - (f.) was developed by or for the Recipient independent of disclosure hereunder as evidence by Recipient's written records.
2. The Receiving Party agrees not to use the Confidential Information provided by the Disclosing Party for any purpose other than the evaluation of the aforementioned business relationship.
3. The Receiving Party agrees to limit distribution of and access to Confidential Information only to employees, officers, and directors within the Receiving Party's immediate organization (and within any parent, subsidiary or affiliated entity) and outside, third party consultants bound by confidentiality requirements no less stringent than those contained within this agreement, and then only to those individuals who have a legitimate "need to know" for the above described evaluation purpose. Each party shall take all reasonable steps to ensure that such employees, whether during or after their employment with the Receiving party, shall keep the Disclosing Party's Confidential Information secret from other entities.

4. Receipt and evaluation of information shall be limited to a one (1) year period following the date of full execution of this Agreement, unless extended by written agreement signed by the parties. Upon thirty (30) days written notice to the other party, either party may terminate this agreement; provided, however, that all obligations of nondisclosure and non-use, as well as those provisions which by their nature should survive termination, shall so survive for a period of three (3) years from the date hereof.
5. The existence, terms, nature, or subject matter of this Agreement are confidential and shall be treated as Confidential Information pursuant to the terms of this Agreement.
6. Confidential Information received from the Disclosing Party and any developments materially derived therefrom are and shall remain the sole property of the Disclosing Party. Nothing herein shall be deemed to constitute by implication or otherwise the license or grant to the Receiving Party by the Disclosing party, except as anticipated for the purpose of this Agreement, of any intellectual property right to or interest in the Disclosing Party's information and/or any information, technology and/or products materially derived or developed therefrom, notwithstanding the exceptions set forth in Paragraph 1 herein. The Receiving Party shall not use, develop, disclose to any third party, and/or commercialize any of the foregoing without the Disclosing Party's written consent. No agency or partnership relationship is created by this Agreement; no warranties, right to use or fitness for any purpose or of any other kind are made by either Disclosing Party; and it is understood that neither party has any obligation to enter into any further agreements with the other related to any business or any other matter.
7. Nothing in this Agreement shall be deemed, by implication or otherwise to convey to the Receiving Party any rights under any patents, patents application, copyrights, trademarks, trade secrets, inventions or any other intellectual property in which the Disclosing Party has rights or interests, nor shall this Agreement be deemed a commitment of any kind by either the Receiving Party or the Disclosing Party to enter in to an future agreement with the other.
8. Each Receiving Party shall exercise due care—not less than the care accorded its own valuable Confidential Information—to prevent the unauthorized disclosure of Confidential Information received from the Disclosing Party hereunder, or its use for any purpose other than evaluation and consultation with the Disclosing party.
9. Each party represents that it has the right to make disclosures under this Agreement; that it will not disclose to the other any information confidential to any third party; and that the terms of this Agreement are not inconsistent with other contractual and/or other legal obligations it may have, or with the policies of any institution with which it is associated.
- 9.1 This Agreement shall be binding upon and inure to the benefit of the successors and assigns of the parties hereto, but neither party shall assign this Agreement without the prior written consent of the other party.

10. Upon termination of either mutual evaluations or business relations between parties, or within thirty (30) days, if otherwise requested by either party, each Receiving Party shall, upon written request, return to the Disclosing Party all written or other physical embodiments of Confidential Information (including tangible materials, unless requested by the Disclosing Party to properly destroy or dispose thereof), together with all full or partial copies thereof, as shall then be in the Receiving Party's possession, except that each party may retain one complete record copy of the other party's Confidential Information for archival purposes and to assure compliance with this Agreement.
11. This Agreement shall be governed and construed in accordance with the laws of the State of Delaware, United States of America without regard to principles of conflict of laws, and this original English language version of the Agreement shall be controlling in all respects. In the event legal action becomes necessary for the enforcement or interpretation of this Agreement such action will be brought in the US District Court for the Western District of Wisconsin, and the parties will submit to the venue and jurisdiction of said courts.
12. No course of conduct or dealing between the parties shall act as a modification or waiver of any provision of this Agreement, unless such modification or waivers are contained in writing and signed by duly authorized representative of each party

OPHIDIAN PHARMACEUTICALS, INC.

By: 

Name: Douglas C. Stafford, Ph.D.

Title: President and CEO

Date: 2/3/00

ALLERGAN, INC.

Approved  
Law Department

By: 

Name: Lauren P. Silvermail

Title: Vice President, Business Development

Date: 2/4/00

AMENDMENT TO CONFIDENTIAL DISCLOSURE AGREEMENT

THIS IS AN AMENDMENT, effective February 10, 2000, to the Confidential Disclosure Agreement which was effective February 3, 2000 between Ophidian Pharmaceuticals, Inc. ("Ophidian") and Allergan, Inc. ("Allergan") (the "Agreement")

The Agreement between the parties is hereby amended as follows:

"Confidential Information" is hereby amended to include all information in Ophidian's possession or under its control which relates in any way to any claims made by, any rights in, or any rights alleged to be owned by (a) any individual, corporation, partnership or other legal entity, or; (2) the United States or an entity, department, laboratory, or facility owned or controlled by the United States (including a U.S. Army Medical Research Institute, the U.S. Army, and/or the U.S. Department of Defense), in any of the inventions disclosed or claimed in any of (1) U.S. patent no. 5,919,665; (2) PCT application WO 96/12802; (3) U.S. patent application serial number 08/704,159, and/or; (4) PCT application WO 98/08540, including all correspondence, memoranda, internal company communications, attorney opinions or advice letters with regard to any such claims, rights or alleged rights.

All other terms and conditions of the Agreement to be unchanged.

ALLERGAN, INC.

By: Lauren P. Silvermail  
Lauren P. Silvermail  
Vice President, Business Development

Date: February 10, 2000

OPHIDIAN PHARMACEUTICALS, INC.

By: Douglas C. Stafford, PhD.

Date: February 10, 2000